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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,437	01/09/2004	Bonita J.M. Ferrie	MM11130-1	8712
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DLA PIPER RUDNICK GRAY CARY US, LLP 4365 EXECUTIVE DRIVE SUITE 1100 SAN DIEGO, CA 92121-2133			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/754,437

Applicant(s)

FERRIE ET AL.

Examiner

Jeanine A. Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-13,23,25,26,36,38,44,48 and 78-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9,11-13,23,25,26,36,38,44,48 and 78-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed August 18, 2005. Currently, claims 1, 3-9, 11-13, 23, 25-26, 36, 38, 44, 48, 78-81 are pending.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.

The rejection over Tachi, Asano, Yuasa have been overcome in view of the amendments to Claims 23, 36.

Maintained Rejections

Priority

4. This application claims priority to provisional application 60/439,188, filed January 10, 2003.

Drawings

5. The drawings are acceptable.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1, 3-9, 11-13, 23, 25-26, 36, 38, 44, 48, 78-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method to determine gender of a canine subject comprising contacting a nucleic acid sample from the canine subject with at least one primer specific for a canine amelogenin gene wherein one primer binds to a sequence of SEQ ID NO: 22 and 23 by using the binding of the primers to detect difference between the canine amelogenin gene on the Y chromosome of the canine amelogenin gene on the X chromosome thereby determining gender of the canine subject.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2b 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. In *The Regents of the University of California v. Eli Lilly* (43 USPQ2b 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a

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nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' required a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. As provided in the written description guidelines, Examples 6 and 7, the single species, namely SEQ ID NO: 22 and 23 encompasses full-length genes and cDNAs that are not described. In the art, gene encompasses naturally occurring regulatory elements and untranslated regions. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 22 and 23 is only a fragment of any full-length gene or cDNA species. The specification specifically teaches that "additional regions of the canine amelogenin gene are likely to be identified from the complete canine amelogenin gene sequence that include nucleotide sequence differences between the copy of the gene on the X chromosome and on the Y chromosome (page 6, para 19). The specification also teaches that the sequences of the instant specification can be used to identify the nucleotide sequence of the entire canine (e.g. dog) amelogenin X chromosome gene and Y chromosome gene (page 25, para 81).

The claims are broadly drawn to canine amelogenin. The genus *canis* encompasses *Canis adustus* (side-striped jackal), *Canis aureus* (golden jackal), *Canis familiaris* (dingo), *Canis latrans* (coyote), *Canis lupus* (gray wolf), *Canis mesomelas*

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(black-backed jackal), *Canis rufus* (red wolf), *Canis simensis* (Ethopian wolf, Abyssinian wolf, Simion jackal, Simion fox). Thus, a canine amelogenin gene encompasses not only each of the domestic dog species, but also each of the other species within the canine genus. Merely considering the *Canis familiaris*, domestic dogs, a review of the AKC (American Kennel Club) website indicates that there are at least 150 breeds of domestic dogs accepted by AKC standards. It is also accepted that the canine species encompasses a very large number of mixed breed dogs which are not recognized by the AKC. Based upon combinations of each of the breed recognized dogs and the combinations of those combinations, the number of canines present in the genus is immense. The specification has not provided the skilled artisan any guidance to detecting differences between amelogenin gene on the Y and X chromosomes. As noted in the alignment provided by Tachi, the wolf and the dog partial DNA sequences of the amelogenin X gene have regions of variability. Tachi teaches that the results strongly indicate that polymorphisms of the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. The specification fails to describe a representative number of canine amelogenin gene on the Y and X chromosome.

Genbank Accession Number AB080686 (3/6/02) is directed to a *canis familiaris* amelx gene for amelogenin, partial cds from a Labrador retriever.

Tachi et al. (J. of Reproduction and Development, Vol. 48, NO. 6, 2002) teaches a partial amelogenin (AMELX) from an extinct wolf species, *Canis lupus hodophilax* Temminck, a Japanese wolf. Tachi teaches an alignment from the domestic dog (*Canis*

familiaris; Labrador retriever) which illustrates differences between the canine amelogenin sequences (see Figure 2 of Tachi).

Asano et al. (Am. Sc. J., Vol. 70, No. 10, pages J351-J362, October 1999) provides an alignment from wolf, dog, human, bovine, pig, mouse and rat amelogenin genes (Figure 6). 3

Weighing all factors, 1) partial structure of the DNAs from the amelogenin gene, 2) breadth of the claims as reading on amelogenin genes yet to be discovered in canine (encompassing dog and wolf species) and 3) the lack of correlation between the structure and function of the genes; in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DNAs which comprise SEQ ID NO: 22 and 23. Applicant has not disclosed any genomic DNA sequences and particularly has not disclosed any intron sequences or regulatory sequences. Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

Response to Arguments

The response traverses the rejection. The response asserts applicants have amended the claims to recite not all canine amelogenin genes, but rather those genes wherein one primer binds to a sequence of SEQ ID NO: 22 and 23. This argument has been considered but is not convincing because the specification does not teach a representative number of canine amelogenin genes. SEQ ID NO: 22 and 23 encompasses full-length genes and cDNAs that are not described. In the art, gene

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encompasses naturally occurring regulatory elements and untranslated regions. There is substantial variability among the species of DNAs encompassed within the scope of the claims because SEQ ID NO: 22 and 23 is only a fragment of any full-length gene or cDNA species.

Further, the claims are directed to primers that bind to SEQ ID NO: 22 and 23. It is noted that "binds" does not require that the primers are complete complements from SEQ ID NO 22 or 23, but rather any primers which may hybridize under low stringency conditions. Therefore, the specification nor the art describe a representative number of primers that would bind to SEQ ID NO: 22 or 23 and would detect differences which are indicative of gender. As discussed above, the specification has not described a representative number of canine amelogenin genes, as the genus encompasses a wide variety and large number of species within the variable genus.

Thus for the reasons above and those already of record, the rejection is maintained.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3-9, 11-13, 23, 25-26, 36, 38, 44, 48, 78-81 are rejected under 35

U.S.C. 112, first paragraph, as containing subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

“Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.”

The nature of the invention and breadth of claims

The claims are drawn to a method to determine gender of a canine subject comprising contacting a nucleic acid sample from the canine subject with at least one probe or primer specific for a canine amelogenin gene by using the binding of the at least one probe or primer to detect difference between the canine amelogenin gene on the Y chromosome of the canine amelogenin gene on the X chromosome thereby determining gender of the canine subject.

The invention is an class of invention which the CAFC has characterized as “the unpredictable arts such as chemistry and biology.” *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The unpredictability of the art and the state of the prior art

Genbank Accession Number AB080686 (3/6/02) is directed to a *canis familiaris* *amelx* gene for amelogenin, partial cds from a Labrador retriever.

Tachi et al. (J. of Reproduction and Development, Vol. 48, No. 6, 2002) teaches a partial amelogenin (AMELX) from an extinct wolf species, *Canis lupus hodophilax* Temminck, a Japanese wolf. Tachi teaches an alignment from the domestic dog (*Canis familiaris*; Labrador retriever) which illustrates differences between the canine amelogenin sequences (see Figure 2 of Tachi). Tachi teaches that the results strongly indicate that polymorphisms of the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. Tachi teaches that further molecular analysis of the intraspecific as well as the interspecific variations in the AMELX DNA will be needed to gain clear insight into the taxonomical and phylogenetic positions in the Japanese wolf.

Asano et al. (Am. Sc. J., Vol. 70, No. 10, pages J351-J362, October 1999) provides an alignment from wolf, dog, human, bovine, pig, mouse and rat amelogenin genes (Figure 6).

Guidance in the Specification and Working Examples

The specification specifically teaches that “additional regions of the canine amelogenin gene are likely to be identified from the complete canine amelogenin gene sequence that include nucleotide sequence differences between the copy of the gene on the X chromosome and on the Y chromosome (page 6, para 19). The specification also teaches that the sequences of the instant specification can be used to identify the

nucleotide sequence of the entire canine (e.g. dog) amelogenin X chromosome gene and Y chromosome gene (page 25, para 81).

The specification teaches that “all canine DNA samples analyzed in this example, were dog DNA samples” (page 27). The specification further teaches DNA was isolated from various male and female dogs (page 28, para 93). The specification fails to teach the number, the species or the similarity between the females analyzed, for example.

The specification teaches that Figure 5 provides a comparison of consensus sequences of canine X (SEQ ID NO: 22) and Y (SEQ ID NO: 23) partial amelogenin sequences. The shaded sequences and gaps indicate differences between the canine AMELX and AMELY sequences.

The guidance provided by the specification amounts to an invitation for the skilled artisan to try and follow the disclosed instructions to make and use the claimed invention. The specification merely discloses an alignment of consensus sequences. The specification fails to provide whether each of the identified differences between the two consensus sequences is X or Y specific.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since there is significant number of parameters which would have to be studied

The claims are broadly drawn to detecting differences between the canine amelogenin gene on the Y chromosome and the canine amelogenin gene on the X chromosome. The specification specifically teaches that “additional regions of the canine amelogenin gene are likely to be identified from the complete canine amelogenin

gene sequence that include nucleotide sequence differences between the copy of the gene on the X chromosome and on the Y chromosome (page 6, para 19). The specification also teaches that the sequences of the instant specification can be used to identify the nucleotide sequence of the entire canine (e.g. dog) amelogenin X chromosome gene and Y chromosome gene (page 25, para 81). While the specification teaches that SEQ ID NO: 22 and 23 may be used to obtain the full length gene, the specification fails to provide any guidance as to the regions in the undescribed sequence which would allow for detecting differences between the Y and the X chromosome. It is unpredictable which sequences, which regions and whether there are additional sequences/regions which may be used to determine gender of the canine subject given the teachings in the specification. The specification has provide no guidance to regions undescribed which would enable detection of gender of a canine subject.

The claims are broadly drawn to canine amelogenin. The genus *canis* encompasses *Canis adustus* (side-striped jackal), *Canus aureus* (golden jackal), *Canus familiaris* (dingo), *Canis latrans* (coyote), *Canis lupus* (gray wolf), *Canis mesomelas* (black-backed jackal), *Canis rufus* (red wolf), *Canis simensis* (Ethopian wolf, Abyssinian wolf, Simion jackal, Simion fox). Thus, a canine amelogenin gene encompasses not only each of the domestic dog species, but also each of the other species within the canine genus. Merely considering the *Canus familiaris*, domestic dogs, a review of the AKC (American Kennel Club) website indicates that are at least 150 breeds of domestic dogs accepted by AKC standards. It is also accepted that the canine species encompasses a very large number of mixed breed dogs which are not recognized by the AKC. Based upon combinations of each of the breed recognized dogs and the

combinations of those combinations, the number of canines present in the genus is immense. The specification has not provided the skilled artisan any guidance to detecting differences between amelogen gene on the Y and X chromosomes. As noted in the alignment provided by Tachi, the wolf and the dog partial DNA sequences of the amelogenin X gene have regions of variability. Tachi further teaches that the results strongly indicate that polymorphisms of the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. Thus, it is unpredictable to the skilled artisan which regions of variability are conserved among the canine amelogenin gene over the genus and which regions are variability between amelogenin gene X and Y. Given the teachings in the specification of a single consensus sequence within the canus family, it is undue and unpredictable which sequences are conserved over the entire genus to enable determining gender of the canine subject with out further experimentation.

The specification teaches that Figure 5 provides a comparison of consensus sequences of canine X (SEQ ID NO: 22) and Y (SEQ ID NO: 23) partial amelogenin sequences. The shaded sequences and gaps indicate differences between the canine AMELX and AMELY sequences. It is unclear whether these shaded sequences are a difference between the consensus sequences of the X and Y chromosomes or whether the shaded sequences only are present in X chromosome or the Y chromosome. The difference being that an alignment showing differences between consensus sequences of the X and Y chromosome would not provide any information regarding whether the nucleotides/sequences present in the X, for example, are present at any frequency in the Y chromosome for example. If the consensus is the most likely nucleotide for the

particular chromosome, this does not indicate that the alternative allele is not present and detection of the alternative allele would indicate a particular gender. If the shaded sequences are only present in X chromosome or Y chromosome, with statistical significance, then the ordinary artisan would be able to detect differences using this guidance. However, the specification fails to make clear or provide any information about the number of dogs (male and female) sampled, the specific breed/species sampled, analysis regarding whether alleles are present in the opposite chromosome, or even whether the allele present is merely an uninformative SNP. The art teaches that polymorphisms exist in nucleic acid sequences with frequency. In the event that only a single or a small number of highly related canines were sampled, the SNP may exist in the consensus sequence which is not related to the gender determination of the canine subject.

The claims are drawn to a method using a probe or primer that specifically binds to SEQ ID NO: 22 and 23, for example. Using a probe that binds to both the Y and X chromosomes would not allow determination of gender of the canine since hybridization to both genders is allowed. Claim 9 specifically is drawn to a method of detecting binding by contacting a sample with a probe or primer specific for canine amelogenin. The claims is broadly drawn to encompass a probe which is to a conserved region between the two sequences. The skilled artisan would be unable to detect gender based upon detecting binding of a probe or primer to a conserved region between X and Y chromosome. Detecting binding of probes and primers to a region of similarity would not enable detect of gender.

Further it is unpredictable, as described above, whether detecting differences would be enabled for other breeds or species, since the art teaches such variability between the species. As Tachi teaches results strongly indicate that polymorphisms of

the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. Tachi teaches that further molecular analysis of the intraspecific as well as the interspecific variations in the AMELX DNA will be needed to gain clear insight into the taxonomical and phylogenetic positions in the Japanese wolf. Thus, detecting differences would not necessarily indicate gender differences, but may detect breed or species differences. Further, the art teaches that further experimentation would be required to practice the claimed invention as broadly as recited.

Each of these described issues would require much inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

In the instant case, as discussed above, in a highly unpredictable art where the specification fails to provide enough guidance or teachings to practice the scope of the claims as broadly as claimed. Further, the prior art and the specification provides insufficient guidance to overcome the art recognized differences in sequences and species, for example. Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner

that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Response to Arguments

The response traverses the rejection. The response asserts "ample teachings with respect to these particular genes on the X and Y chromosome and primers useful for amplifying such sequences" have been provided. This argument has been considered but is not convincing because the specification fails to provide clear guidance to the skilled artisan to determine gender. As provided in the rejection above, "the specification fails to make clear or provide any information about the number of dogs (male and female) sampled, the specific breed/species sampled, analysis regarding whether alleles are present in the opposite chromosome, or even whether the allele present is merely an uninformative SNP. The art teaches that polymorphisms exist in nucleic acid sequences with frequency. In the event that only a single or a small number of highly related canines were sampled, the SNP may exist in the consensus sequence which is not related to the gender determination of the canine subject." Also, the rejection above, states, "as Tachi teaches results strongly indicate that polymorphisms of the nucleotide as well as the amino acid sequence might exist in this particular region of AMELX, depending upon the different breeds of domestic dogs, *Canis familiaris*. Tachi teaches that further molecular analysis of the intraspecific as well as the interspecific variations in the AMELX DNA will be needed to gain clear insight into the taxonomical and phylogenetic positions in the Japanese wolf. Thus, detecting differences would not necessarily indicate gender differences, but may detect breed or species differences."

While the specification provides a "consensus" sequence for AMELX and a "consensus" sequence for AMELY. Neither the specification nor the art specifically provide any guidance to the skilled artisan how to use the claimed invention without further experimentation. The art suggests that the AMELX and AMELY genes are variable between species. The specification nor the prior art suggest how the skilled artisan would determine whether differences are the result of natural variation between sequences or variations are related to gender differences. As discussed above, it is unclear what the consensus sequence represents. Further unpredictable and undue experimentation would be required to determine the sequences of various species which would allow the determination/detection of genders across the "canine" genus.

Thus for the reasons above and those already of record, the rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3-9, 11-13, 23, 25-26, 36, 38, 44, 48, 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The claims are drawn to "one primer binds to a sequence of SEQ ID NO: 22 and SEQ ID NO: 23." It is unclear whether one primer is to bind to each of these sequences or a conserved primer between the two sequences. As written it appears

that one primer should bind to SEQ ID NO: 22 and 23, however, it could be unclear how the ordinary artisan would use the same primer to detect differences between the two canine amelogenin genes to detect gender differences. Clarification is request.

Conclusion

9. No claims allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.


Jeanine Goldberg
Primary Examiner
October 24, 2005